UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,928	10/05/1998	NORIO INOMATA	001560-336	8658

21839 7590 03/04/2005

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/171,928	INOMATA ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued examination under 37 CFR 1.114 after final rejection

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/03/2004 has been entered.

Status of Claims

2. Claims 8-11,21 are currently pending.

Claim Rejections - 35 USC § 112, first paragraph.

3. Claims 8-11,21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of cardiac hypertrophy is rats using ANP at dosages which do not cause hypertensive or diuretic effect, does not reasonably provide enablement for (1) treatment of cardiac hypertrophy with ANP in species other than rats at dosages which do not cause diuretic and hypotensive effects; (2) treatment of cardiac hypertrophy with agents other than ANP at dosages which do not cause diuretic and hypotensive effects. The rejection is maintained for the reasons of record and further in view of the following.

Applicant continues to argue that results obtained from rat are sufficient to enable the same results in treatment of other subjects including human and that rat model is well excepted model of hypercardia in humans. Examiner reiterates that the issue here is whether ANP is capable of acting without causing diuretic and hypotensive effects in humans (or other species), which is the critical distinction of the claimed method. At

issue is not the interspecies differences or similarities in the etiology of the disease but rather whether the mechanism of action of ANP is the same. Applicant refers to Blaine reference which provides example on rats and then claims method of treatment without animal limitation. However, as discussed before, applicants themselves were arguing previously not to consider reference of Blaine et al because it teaches diuretic effect. Further, applicants argued in the response filed 07/25/2002 that the finding of the effect of ANP without involving hypotensive and diuretic effect is unexpected and unusual. Hence, the examiner has reasons to believe that effect of the same agent, namely ANP, might be different in different species, and maintains that since the art is deemed unpredictable in regard to ANP acting without involving hypotensive and diuretic effects, and in the absence or working examples and sufficient guidance, specification does not commensurate with the scope of invention claimed.

Applicant alleges that Examiner has not met burden of providing scientific reasoning. The reasons for this statement are not clear, given that the Examiner has consistently reiterated scientific reasoning during the course of prosecution.

As for the second part of the rejection, applicant now provides discussion of natriuretic peptide receptors known at the time the invention was made and conclude that, as the receptors are the same for all agents that increase cGMP activity, "it is believed that in all mammals, ANP and BNP exhibit their biological ativity via GC-A receptor". If this statement implies that the mechanism of action is the same for all agents and in all species, Examiner is confused. As discussed above, even for the same agent, ANP, applicant argued that that the finding of the effect of ANP without involving hypotensive and diuretic effect is unexpected and unusual and that Blaine reference should not be considered because it teaches ANP diuretic effect (does it confirm then that the same effect is indeed present in all species and for all agents?)

Further, to demonstrate that even for ANP, ANP species of different origin may have different effect, Examiner cited Squadrito et al reference showing difference in effects of ANP species derived from different sources. Applicant provided no comments in regard to Squadrito et al reference. Examiner emphasizes that, again, the issue is not the similarity of known effects between various natriuretic peptide receptor ligands, but whether these different ligands will be capable of acting without causing diuretic and hypotensive effects. This question is not addressed in applicant's response.

Claim Rejections - 35 U.S.C. § 102

4. Claims 8-11, 21 remain rejected under 35 U.S.C. 102(b) as anticipated by Blaine et al. (US Patent 4652549) as evidenced by Espiner.

The rejection is maintained for the reasons of record. Applicant argues that the Blaine reference does not refer to treatment of chronic cardiac disfunctions, The Blaine reference is drawn to treatment of cardiac hypertrophy in general and is not limited to treatment of acute or transient cardiac hypertrophy as opposed to chronic disease. Note, that the applicants themselves disclose in the specification that cardiac disfunction is a disorder on which various cardiac diseases are based, one of which is chronic heart failure (i.e., disease addressed in the instant claims). See specification, p.4, lines 31-32.

Therefore, the referenced method anticipates the instantly claimed method of treatment of heart disease based on cardiac hypertrophy comprising administration of a substance that acts on natriuretic receptor, guanylyl cyclase A and is able to accelerate production of cGMP.

5. This is a RCE of applicant's earlier Application No. 09/171928. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb